

REMARKS

The Final Office Action dated May 10, 2011 has been received and carefully reviewed.

Claims 23-24 are rejected under 35 USC 112, first paragraph, as being unsupported by the description of the piston recited in these claims, and the drawing is objected to under 37 CFR 1.83(a) as failing to show the piston.

It is submitted that the rejection and objection are obviated by the present amendment.

Submitted herewith is a new drawing sheet depicting Figure 6, which shows the piston, as recited in the injection syringe of claims 23-25.

It is submitted that no new matter has been entered into the application by the amendment to the drawings and specification, because the piston is sufficiently described as part of the claimed injection syringe on page 7, lines 21-27, of the original disclosure. The structure of a syringe is well known in the art, and, as such, need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

The specification has been amended on page 5 to include a description of Figure 6, and on page 7, lines 21-27, to include

reference numerals for the parts which make up the syringe, as depicted in Figure 6.

In view of the above amendments and remarks, it is respectfully submitted that the rejection of claims 23-24 under 35 USC 112, first paragraph, and the objection to the drawing under 37 CFR 1.83(a), have been overcome. Favorable reconsideration and withdrawal of the rejection and objection are thus urged.

The rejection of claims 16-21 under 35 USC 103(a) as being unpatentable over Yoshikawa et al. (US 5,637,399) in view of Preissman (US 6,348,055) is maintained.

More particularly, the Examiner takes the position (page 4 of the final Office action) that Yoshikawa et al. (hereinafter "Yoshikawa") discloses a needle having a wall comprising a polyaryletherketon (PEEK) in contact with the central lumen of the needle, the needle further comprising at least three reinforcement wires embedded in the polymer, and extending parallel to the longitudinal axis of the needle, and being even-tensioned throughout the length of hollow body (in reference to Yoshikawa at col. 1, lines 47 through col. 2, line 4), and distributed such that any pair of wires defines an identical center angle (with reference to Yoshikawa at col. 3, lines 40-50).

The Applicant respectfully disagrees with the position taken by the Examiner.

Indeed, although Yoshikawa discloses a synthetic resin needle which may be made with a number of synthetic resins including PEEK (col. 2, lines 14 and 27), the resin is actually reinforced with combustible fibers (col. 2 lines 30-31).

In sharp contrast, the present invention requires wires, which a skilled worker would understand to be made of metal. In this regard, the Examiner's attention is directed to the definition of "wire" from the Wikipedia website www.wikipedia.org: *"A wire is a single, usually cylindrical, elongated strand of drawn metal. Wires are used to bear mechanical loads and to carry electricity . . . "*

This constitutes an essential technical difference over Yoshikawa.

Further the fibers of Yoshikawa, depending of the kind of the synthetic resin used, represent from 10 to 80% by volume, preferably 30 to 80% by volume, more preferably 40 to 70% by volume of the resin material (see col. 2, lines 51-56 of Yoshikawa).

To reach such a level of volume, bundles of thousands of fibers would have to be used, as shown in the examples. For instance, in Example 1 of Yoshikawa, a bundle of 7,800 carbon

fibers is used, the fibers being uniformly dispersed, and the synthetic resin is introduced so as to impregnate the carbon fibers (see col. 3, lines 65-66, col. 4, lines 1-4; and col. 4, lines 6-11).

In view of this teaching of Yoshikawa, the present claim 16 limitation of *"at least three reinforcement wires embedded in the polymer and extending parallel to the longitudinal axis X-X', and being even-tensioned throughout the length of hollow body and distributed such that any pair of said wires defines an identical center angle"* clearly is not disclosed or suggested by Yoshikawa.

It is clear that the thousands of fibers uniformly distributed throughout the needle resin body of Yoshikawa's needle cannot meet Applicant's claim requirement that any pair of the wires define an identical center angle. Furthermore, no real center angle can be defined for most of the fibers of Yoshikawa.

In addition, as discussed above, the Yoshikawa reinforcing fibers are synthetic and are combustible fibers.

In the context of Applicant's invention, the wires have the usual meaning of being metallic wires, which are capable of being depyrogenized without becoming deformed, this being an important properties of the needle of the invention (see

specification at page 2, lines 1 to 13). These properties result from a combination of the PEEK material with the reinforcing wires located equidistantly (see page 2, line 34, to page 3, line 2; and page 6, lines 14 to 31), the best embodiment being a wire made of 316 stainless steel (page 6, lines 29-31; and claim 18).

With the combustible fibers required by Yokshikawa, however, it is not possible to obtain a resistance to deformation during depyrogenizing, contrary to the situation obtained in the present invention.

According to Applicant's invention, the wires, being equidistantly disposed, have a dilation coefficient similar to the dilation coefficient of PEEK, which cannot be said of the combustible fibers used by Yoshikawa, such as carbon fibers or others.

Accordingly, with Applicant's invention, during heating up to 250°C for the purposes of sterilizing or depyrogenizing, no torsion or deformation of the invention needle is noticed.

In view of all of the above, it is submitted that Yoshikawa does not disclose or suggest the presently claimed invention.

The Preissman reference does not fill the gaps left by Yoshikawa.

Preissman relates a non-compliant system for delivery of implant material from a high pressure applicator to an implant delivery device. As such, there exists no motivation for a person of ordinary skill in the art to modify the needle of Yoshikawa with Preissman's teaching of a non-compliant system.

Furthermore, Preissman teaches, in the embodiment of Figures 8 and 9, a tubing 70 which can be made of different polymers, including PEEK. However, when the material is made of PEEK, no reinforcing coil is used (see col. 9, lines 44-45). Accordingly, Preissman teaches away from the invention by teaching that when the tubing is made of PEEK, no reinforcing coil has to be present.

Finally, it should be observed that Preissman supports Applicant's position that a wire is metallic, by virtue of the sentence of col. 9, lines 55-55, where it is stated: "Coil 78 is preferably a flat wire spring, preferably comprising stainless steel".

In view of the above remarks, it is submitted that a combination of Yoshikawa and Preissman would not result in the Applicant's invention, especially in the light of Preissman's disclosure that no reinforcing coil is used with PEEK. This would suggest to a person of ordinary skill in the art that no reinforcing coil should be used with PEEK.

In view of all of the above, it is submitted that the rejection under 35 U.S.C. 103(a) is unsustainable, and should be favorably reconsidered and withdrawn.

Applicant submits that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Applicant hereby petitions the Commissioner for Patents to extend the time for reply to the Final Office action dated May 10, 2011, for one (1) month from August 10, 2011, to September 10, 2011. Payment is being made by electronic funds along with the filing of this paper.

Respectfully submitted,



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